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TECHNICAL ISSUES

Compression coil provides increased lead control in extraction procedures

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Aims We investigated a new lead extraction tool (Compression Coil; One-Tie, Cook Medical) in an experimental traction force study.

Methods and results On 13 pacemaker leads (Setrox JS53, Biotronik) traction force testing was performed under different configurations. The leads were assigned to three groups: (i) traction force testing without central locking stylet support ($n = 5$), (ii) traction force testing with the use of a locking stylet (Liberator, Cook Medical) and a proximal ligation suture ($n = 4$), (iii) traction force testing with the use of a locking stylet and a compression coil ($n = 4$). The following parameters were obtained for all groups: stress–strain curves, maximal forces, elastic modulus, post-testing lead length and lead elongation. In Groups 2 and 3 retraction of the locking stylet within the lead was measured [lead tip-locking stylet distance (LTLSD)]. Maximal forces for the three groups were: (i) 28.3 ± 0.3 N; (ii) 30.6 ± 3.0 N; (iii) 31.6 ± 2.9 N (1 vs. 2, $P = 0.13$; 1 vs. 3, $P = 0.04$; 2 vs. 3, $P = 0.65$). Elastic modulus was (i) 22.8 ± 0.1 MPa; (ii) 2830.8 ± 351.1 MPa; (iii) 2447.0 ± 510.5 MPa (1 vs. 2, $P < 0.01$; 1 vs. 3, $P < 0.01$; 2 vs. 3, $P = 0.26$). Mean LTLSD in Group 2 was 19.8 ± 3.2 cm and was 13.8 ± 1.7 cm in Group 3 ($P = 0.02$). The ratio of LTLSD/post-testing lead length was 0.37 ± 0.03 for Group 2 and 0.24 ± 0.03 for Group 3 ($P < 0.01$).

Conclusion The application of a compression coil leads to an increased lead control expressed by less retraction of the locking stylet within the lead. This enables improved central support of extraction sheaths in the case of challenging extraction procedures.

Keywords Lead extraction • Pacemaker • ICD • Compression coil

Introduction

Basic principles of lead extraction procedures are traction and counterpressure (along the course of a lead) or countertraction (at the tip of a lead). If traction alone is not sufficient to extract a targeted lead, non-powered and powered extraction sheaths are used to dissect the leads free of fibrotic adhesions along the course of a lead (counterpressure) or at the lead tip close to the myocardial interface. The applied traction must be sufficient to allow the extraction sheath to follow the course of the lead, especially at the curves of the vascular system.[1] In this context the lead is the rail for the sheath and prevents vascular or myocardial injury due to the extraction sheath. This is referred to as the 'rail effect'.[2]

In order for a lead to serve as an adequate rail it is important for the operator to have control over the complete length of a targeted lead from the proximal end to the distal tip of the lead. There are different locking stylets available to support lead control and the rail effect of a targeted lead. Furthermore locking stylets transfer traction forces from the end to the tip of a lead or to the complete course of a lead according to the anchoring mechanism of the locking stylet. In this study the Liberator® locking stylet (Cook Medical, USA) was used, which anchors exclusively in the distal part of the lead. Alternatively, there exists the LLD® locking stylet (Spectranetics), which anchors along the complete course of the lead. The LLD® locking stylet was not investigated in this study.

Just recently a new tool supporting lead extraction procedures, a so-called compression coil (One Tie, Cook Medical, USA) was introduced to the market. It binds the proximal parts of a targeted lead and the locking stylet together and is supposed to increase lead control and therefore improve the rail effect during lead

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What's new?

- Traction force bench testing study of a new extraction tool.
- Investigation of the mechanism of action of a new extraction tool (compression coil).
- The application of a compression coil leads to an increased lead control in transvenous lead extraction procedures.

extraction procedures.[3] To the best of our knowledge, a study investigating the mechanism of action of this new extraction tool has not been published yet.

In this benchtesting study we analysed the mechanism of action of compression coils.

Methods

On 13 pacemaker leads (Setrox JS53, Biotronik) traction force testing was performed under different configurations. According to the configuration, the leads were assigned to three groups: (i) traction force testing without central support of a locking stylet ($n = 5$), (ii) traction force testing with the use of a locking stylet (Liberator, Cook Medical) and a proximal ligation suture ($n = 4$), and (iii) traction force testing with the use of a locking stylet (Liberator) and a compression coil (One-Tie, Cook Medical) ($n = 4$).

The measurements of traction forces were verified by Shimadzu AGS-X 5 kN load cell tensile testing machine (Shimadzu). The lower part of the lead was rigidly fixed to a clam. The upper part had two fixation options: for a lead without locking stylet support, it was similarly rigidly fixed to the upper clam; for configurations with the use of a locking stylet with or without compression coil, the proximal part of the locking stylet was fixed rigidly to an especially constructed rectangular fixation block (120 × 24 × 4 mm) (*Figure 1*). The tensile strength measurements were conducted with a speed of 400 mm min^{-1} with strain values up to 70%.

The mechanical tests were characterized by maximal traction forces (N), elastic modulus (Young's modulus), post-test lead length and lead elongation values. The elastic modulus (Young's modulus) of a material is defined as the slope of the stress–strain curve in the elastic region. It is a measure of the stiffness of a component and therefore a stiffer material will have a higher Young's modulus. The unit of the elastic modulus is Pascal (Pa).[4] Furthermore in Groups 2 and 3 dislocation of the locking stylet within the lead at maximal forces was measured [lead tip-locking stylet distance (LTLSD)].

Statistics

Data were analysed using the SPSS software Version 22 (IBM Corporation). Continuous variables are presented as mean ± standard deviation. Two sample t-tests were performed to analyse the differences between groups. A P-value of <0.05 was considered significant.

Results

The mean maximal force applied in Group 1 was 28.3 ± 0.3 N, in Group 2, 30.6 ± 3.0 N and in Group 3 31.6 ± 2.9 N. There were no significant differences between Groups 1 and 2 ($P = 0.13$) as well as between Groups 2 and 3 ($P = 0.65$). When comparing the differences between Group 1 and 3, Group 3 showed significantly higher maximal forces ($P = 0.04$) (*Table 1*).

The mean value of the elastic modulus was 22.8 ± 0.1 MPa in Group 1, 2830.8 ± 351.1 MPa in Group 2 and 2447.0 ± 510.5 MPa.

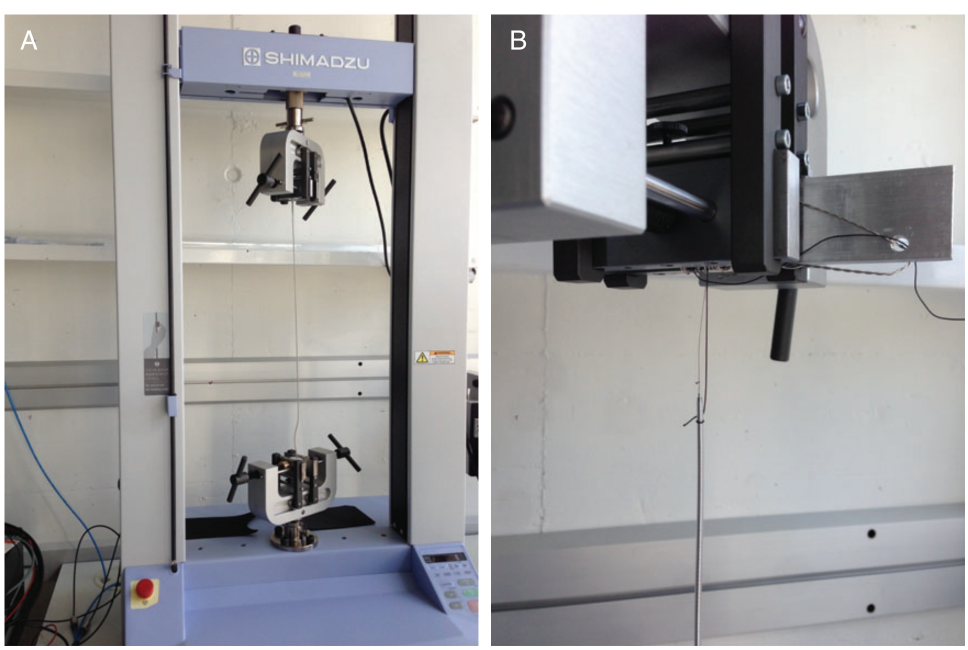

Figure 1 (*A*) Experimental setup of traction force testing with the use of the Shimadzu AGS-X 5 kN load cell tensile testing machine (Shimadzu). (*B*) The proximal part of the locking stylet was fixed rigidly to an especially constructed rectangular fixation block (120 × 24 × 4 mm).

Table 1 Mechanical properties of the tested lead configurations

Parameter	Group 1 (LO)	Group 2 (LLS)	Group 3 (LLSCC)	*P*-value
Average maximal force (*N*)	28.3 ± 0.3	30.6 ± 3.0	31.6 ± 2.9	1 vs. 2, $P = 0.13$ 1 vs. 3, $P = 0.04$ 2 vs. 3, $P = 0.65$
Average elastic modulus (MPa)	22.8 ± 0.1	2830.8 ± 351.1	2447.0 ± 510.5	1 vs. 2, $P < 0.01$ 1 vs. 3, $P < 0.01$ 2 vs. 3, $P = 0.26$

LO, lead only; LLS, lead with locking stylet; LLSCC, lead with locking stylet and compression coil.

When comparing the three groups, differences in the mean elastic modulus between Groups 1 and 2 as well as Groups 1 and 3 were significant (1 vs. 2, $P < 0.01$; 1 vs. 3, $P < 0.01$). Comparing the mean elastic modulus between Groups 2 and 3 revealed no significant differences (2 vs. 3, $P = 0.26$) (*Table 1*).

With regard to lead elongation, results between the groups were comparable, except for the difference between Groups 1 and 3, which showed a significantly higher mean elongation in Group 3. The average lead elongation in Group 1 was 12.3 ± 0.3 cm, in Group 2 it was 10.3 ± 4.9 cm ,and in Group 3 it was 13.8 ± 0.5 cm (1 vs. 2, $P = 0.37$; 1 vs. 3, $P < 0.01$; 2 vs. 3, $P = 0.20$).

In Groups 2 and 3 the LTLSD after traction force testing was measured. The LTLSD is the distance of retraction of the locking stylet within the inner lumen of the lead after completion of traction force application. These measurements revealed the following results. Mean LTLSD in Group 2 was significantly higher than in Group 3 (19.8 ± 3.2 cm vs. 13.8 ± 1.7 cm; $P = 0.02$). The ratio of LTLSD and post-test lead length was 0.37 ± 0.03 for Group 2 and 0.24 ± 0.03 for Group 3 ($P < 0.01$) (*Table 2*).

Table 2 Comparison of post-testing lead length, lead elongation, and locking stylet retraction between Group 2 (leads with locking stylet support) and Group 3 (leads with locking stylet and compression coil support)

Parameter	Group 2	Group 3	*P*-value
Post-testing lead length (LL) (cm)	53.3 ± 4.9	56.8 ± 0.5	0.20
Lead elongation (LE) (cm)	10.3 ± 4.9	13.8 ± 0.5	0.20
LTLSD (cm)	19.8 ± 3.2	13.8 ± 1.7	0.02
Ratio LL-LTLSD	0.37 ± 0.03	0.24 ± 0.03	<0.01

Discussion

The results of lead extraction procedures are nowadays on a high standard with high success rates and low complication rates.[5–8] It is also well known that, despite the good success rates reported, there remain challenging lead extraction procedures, especially in leads with implant durations of ≥10 years.[8,9] Another fact is that lead extraction procedures may rarely result in major, life-threatening complications due to myocardial or vascular injury. In case such complications arise they are associated with a high mortality rate even when appropriate cardiac surgical management was immediately available.[10,11] Especially in the superior vena cava region injuries may be due to insufficient guidance of extraction sheaths along the course of the lead caused by inappropriate rail effect. For safety reasons and the avoidance of life-threatening injuries during lead extraction procedures it appears to be of utmost importance to obtain a maximum degree of lead control.

In this bench testing study the mechanism of action of compression coils as additional tools for improved lead control was investigated on 13 pacemaker leads (Setrox JS53, Biotronik, Germany).

When evaluating the stress–strain curves and the elastic modulus, we were able to show that, in case of traction force application on leads alone without locking stylet support, these leads resisted the applied forces through the silicone insulation layer. Traction force application follows the stress–strain curve characteristic for silicone rubber mechanical behaviour. Elastic behaviour of the lead remained up to 20% strain, upon that an irreversible plastic deformation occurred (*Figure 2*). The leads showed maximum resistance towards the traction forces up to 30 N. The plastic deformation of silicone was irreversible, i.e. after removal of the traction force the lead remained in the stretched form. The literature data on silicone rubber mechanical properties correlate with the obtained stress–strain curves, i.e. Young's modulus lies in the range of 0.001–0.05 GPa.[12] In the tested samples that value corresponded to ~ 0.02 GPa (calculated from an area of 5.5 mm^2, strain 10%, force 5 N).

The leads with the central support of a locking stylet or the leads with a locking stylet and the additional fixation with the compression coil possessed elastic behaviour characteristic for metal wires. The stress–strain curve could be divided into two characteristic parts: metal wire (elastic and plastic regions) and silicone shell (elastic and plastic regions). Primarily the metal wire of the locking stylet deforms elastically providing traction forces resistance of 7.5 N. For instance, steel has Young's modulus of 190 GPa,[13,14] thus *Figure 3* shows the model metal wire behaviour of an area of 1 mm^2 which is overlapping with the stress–strain curve for leads with locking stylet support up to a deformation of 2%. Further deviation (i.e. reduction of Young's modulus) could be explained by the silicone insulation layer material impact. After the collapse of the metal wire, the silicone shell takes over the resistance against the mechanical stresses occurring during the traction force testing.

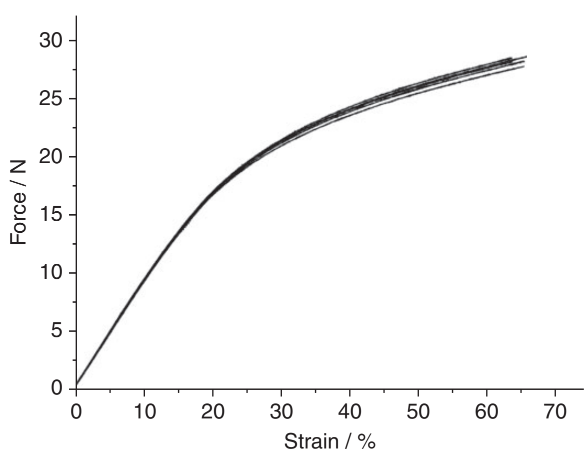

Figure 2 Traction force–strain curves for leads only (Setrox JS 53, Biotronik). The deformation profiles are characteristic for the mechanical behaviour of silicone rubbers.

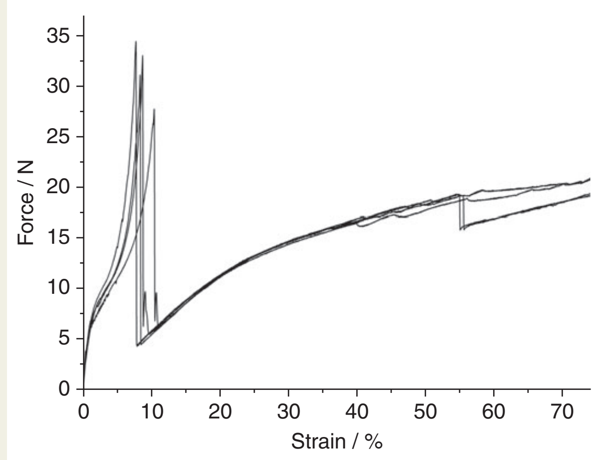

Figure 4 Traction force–strain curves for leads (Setrox JS 53, Biotronik) with the central support of a locking stylet (Liberator, Cook Medical) and an additional fixation with a compression coil (One Tie, Cook Medical).

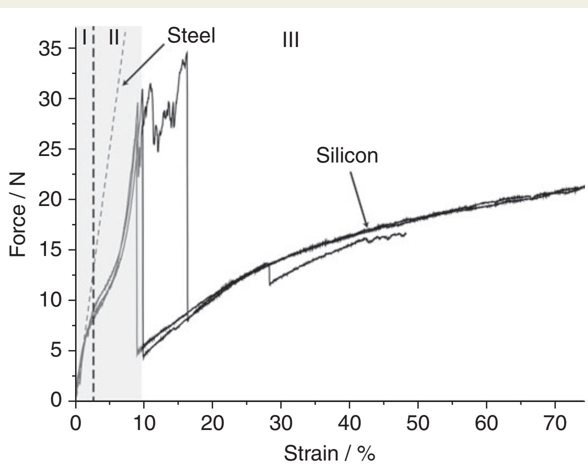

Figure 3 Traction force–strain curves for leads (Setrox JS 53, Biotronik) with the central support of a locking stylet (Liberator, Cook Medical) and a proximal fixation suture. The deformation profiles consist of characteristic regions: I—elastic deformation characteristic for metal wires, II—plastic behaviour of metal wire, and III—deformation of the silicone shell of the lead. The stress–strain curve of steel was added as a comparison.

The results showed that leads with the central support of a locking stylet improve the resistance to extraction forces acting on the lead (up to 35 N, see *Figure 3*). The additional fixation with a compression coil does not relevantly change the resistance to extraction forces (see *Figure 4*). However, the leads with locking stylet and compression coil support were capable of withstanding high traction force values while maintaining low strain values (<10% vs. 60% see *Figures 3 and 4*).

The retraction of locking stylets during a lead extraction procedure, especially in challenging cases with extensive adhesions, may occur, irrespective of the kind or manufacturer. If this occurs loss of lead control at the tip of the lead over the distance of retraction is the consequence. This may subsequently either lead to the damage of the lead insulation with possible failure of the extraction procedure or, even worse, to an injury due to an inadequate rail effect of the lead to an extraction sheath. With regard to the retraction of the locking stylet within the lead, we were able to show that the additional fixation with a compression coil led to a significant reduction in retraction at maximal traction forces in combination with the Liberator® locking stylet (Cook Medical, USA). Based on these results it may be stated that the application of a compression coil leads to an improvement of lead control and therefore fulfils its intended effect.

On the other hand the phenomenon of locking stylet retraction, especially in cases of extensive fibrotic adhesions, shows a suboptimal performance of current locking stylets. This should encourage scientists and manufacturers to improve locking stylet mechanisms in such a way that retraction at high traction forces is minimized or eliminated.

The limitation of this bench testing study is the nature of *ex-vivo* testing with the lack of accounting for possible interactions due to the human body. Furthermore traction force application was on a straight lead, which does not represent the course of the lead within the human body and traction force distribution *in-vivo* may be different. It should also be pointed out that this study was performed merely with the Liberator® locking stylet (Cook Medical) and that these results cannot be transferred to other locking stylet systems with a different anchoring mechanism. This fact should however be motivation for further future investigations with different locking stylet systems. Despite these limitations we do think that the results may be transferred into clinical application.

Conclusion

The application of a compression coil leads to an increased lead control expressed by less retraction of the locking stylet within the lumen of the lead at maximal traction force. This enables improved lead control at the tip of a targeted lead and subsequent improved central support of extraction sheaths in the case of challenging extraction procedures.

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